



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 170, 177, and 189

[Docket No. FDA-2015-F-0537]

Natural Resources Defense Council et al.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by the Natural Resources Defense Council, Center for Food Safety, Clean Water Action, Children's Environmental Health Network, Center for Science in the Public Interest, Breast Cancer Fund, Center for Environmental Health, Environmental Working Group, and Improving Kids' Environment, proposing that we amend our regulation to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers, revoke the Threshold of Regulation exemption No. 2005-006 to no longer exempt the use of sodium perchlorate monohydrate as a conductivity enhancer in antistatic agents for use in finished articles in contact with dry foods, and issue a new regulation to prohibit the use of perchlorate in antistatic agents for use in food-contact articles. We are requesting comments on the petition and establishing a comment period of 60 days from the date of publication of this notice.

DATES: The food additive petition was filed on December 31, 2014. Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA-2015-F-0537 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul Honigfort, Center for Food Safety and Applied Nutrition (HFS-275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1206.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 4B4808), submitted by the Natural Resources Defense Council, 1152 15th St., NW., suite 300, Washington, DC 20005; Center for Food Safety, 303 Sacramento St., Second Floor, San Francisco, CA, 94111; Clean Water Action, 1444 I St. NW., suite 4000, Washington, DC 20005-6538; Children's Environmental Health Network, 110 Maryland Ave. NE., suite 402, Washington, DC 20002; Center for Science in the Public Interest, 1220 L St. NW., suite 300, Washington, DC 20005; Breast Cancer Fund, 1388 Sutter St., suite 400, San Francisco, CA 94109-5400; Center for Environmental Health, 2201 Broadway, suite 302, Oakland, CA 94612; Environmental Working Group, 1436 U St. NW., suite 100, Washington, DC 20009; and Improving Kids' Environment, 1915 West 18th St., Indianapolis, IN 46202. The petition proposes that we: (1) Amend 21 CFR 177.1210 to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers; (2) revoke the Threshold of Regulation (TOR) exemption No. 2005-006 to no longer exempt from regulation under the food additive provisions of the FD&C Act the use of sodium perchlorate monohydrate as a conductivity enhancer in antistatic agents for use in finished articles in contact with dry foods; and (3) issue a new regulation in 21 CFR part 189, subpart D (Substances Prohibited from

Indirect Addition to Human Food Through Food-Contact Surfaces) to prohibit the use of perchlorate in antistatic agents for use in food-contact articles.

Pursuant to § 189.1(c), we are requesting comments on the petition and establishing a comment period of 60 days from the date of publication of this notice.

II. Amendment of 21 CFR 177.1210

The petition asks us to amend § 177.1210 so that it would no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers in accordance with procedures specified in 21 CFR 171.130 for amending or revoking a food additive regulation. Specifically, the petition notes that new perchlorate toxicity data are now available which support the requested amendment of § 177.1210. If we determine that new data are available regarding the toxicity of potassium perchlorate that justify amending § 177.1210 so that it would no longer allow the use of potassium perchlorate, we will publish such an amendment of the regulation in the Federal Register, as set forth in § 171.130 and § 171.100.

III. Revocation of TOR Exemption No. 2005-006

The petition asks us to revoke TOR exemption No. 2005-006 to no longer exempt from regulation under the food additive provisions of the FD&C Act the use of sodium perchlorate monohydrate as a conductivity enhancer in antistatic agents for use in finished articles in contact with dry foods. Specifically, the petition notes that new toxicity and exposure data on perchlorates are now available which support the requested revocation of TOR exemption No. 2005-006.

The procedures for revoking a TOR exemption are specified in § 170.39(g), which states that if we tentatively conclude that available information on the dietary concentration or safety of sodium perchlorate monohydrate no longer supports a TOR exemption from the food additive

regulations, we will notify the persons who requested the exemption of our decision and will provide them with an opportunity to show why the exemption should not be revoked. If after following all of the other procedures required by § 170.39(g) we decide to revoke TOR exemption No. 2005-006, we will publish a notice to that effect in the Federal Register.

IV. Issue of a New Regulation in 21 CFR 189 Subpart D

The petition asks us to issue a new regulation in part 189, subpart D to prohibit the use of perchlorate in antistatic agents for use in food-contact articles. Specifically, the petition notes that new toxicity and exposure data on perchlorates are now available which support the issue of such a regulation.

The procedures for issuing a new regulation in part 189 are set forth in § 189.1. Section 189.1(a) states that “food ingredients” may be prohibited from uses in human food based on “a determination that [the food ingredients] present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in human food.” Section 189.1(c) requires FDA to publish the petition for comment if the petition contains reasonable grounds to that effect. Accordingly, we request comments on the petition with respect to the petitioners’ request for the issuance of a new regulation in part 189, subpart D to prohibit the use of perchlorate in antistatic agents for use in food-contact articles.

We have determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Comments

Interested persons may submit either electronic comments to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only

necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: March 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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